Medications and Older Adults

Mary Parker of Oak Ridge, Tenn., is quick to joke about her health problems. Her vibrant smile and upbeat attitude belie her age.

But when she was 77 years old she had a health problem she didn't find amusing. The medication she took for her swollen sinuses left her so weak and dizzy she couldn't get out of bed.

"I felt like I wanted to die," she remembers. "It was awful."

She learned an important lesson from the episode. She thinks twice before taking any medication, questions her doctors and pharmacists, and reviews all of her medications regularly with her primary physician.

Parker's attitude is a good one for older adults to have, experts say. As people age, they often develop a number of problems taking medications. Being aware that problems may occur is the first way to minimize them.

"You are a partner in your healthcare," urges Madeline Feinberg, Pharm.D., a pharmacist and director of the Elder Health program of the University of Maryland School of Pharmacy. "This is a partnership between you, your doctor, and your pharmacist. You need to be assertive and knowledgeable about the medications you take."

FDA is also working to make drugs safer for older adults, who consume a large share of the nation's medications. Adults over age 65 buy 30 percent of all prescription drugs and 40 percent of all over-the-counter drugs.

"Almost every drug that comes through FDA [for approval] has been examined for effects in the elderly," says Robert Temple, M.D., associate director for medical policy in FDA's Center for Drug Evaluation and Research. "If the manufacturer hasn't done a study in the elderly, we ask for it."

More than 15 years ago, the agency established guidelines for drug manufacturers to include more elderly patients in their studies of new drugs. Upper age limits for drugs were eliminated, and even patients who had other health problems were given the green light to participate if they were able. Also, drugs known to pass primarily through the liver and kidneys must be studied in patients with malfunctions of those organs. This has a

Protecting Older Patients

To help ensure the safe and effective use of prescription drugs in older people (specifically, aged 65 and older), a rule finalized by FDA in August 1997 requires drug companies to include a separate "Geriatric Use" section in their drugs' labeling. Drug companies do not have to perform additional studies like the pediatric rule requires, but must include available information in a specific format and location.

"If the information is dispersed throughout the whole label, it doesn't make for a user-friendly information source," says Robert Michocki, a clinical pharmacist and professor at the University of Maryland's school of pharmacy. "People are busy. Physicians don't sit down and read the whole drug label. They try to read the important sections that answer questions like 'what's the dose?' or 'what are the side effects?'

While drugs for everything from heart problems and high blood pressure to pneumonia and the flu can be lifesavers for older people, the dangers of medicine can be magnified in this population, too.

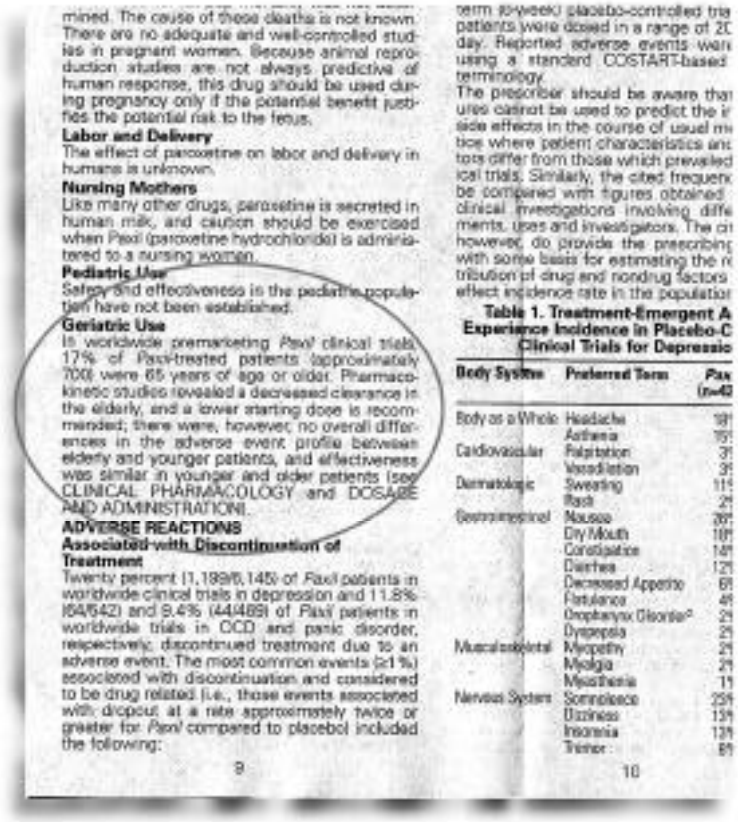
One reason for the increased risk is people's changing physiology as they get older, says Charles Ganley, M.D., FDA's medical team leader for cardiorenal drug products. For example, he says, certain drugs that are eliminated from the body by the kidneys could cause problems in the elderly because kidney function can decline with age.

Also, the elderly take more medicines than any other age group—around 30 percent of the prescription drugs sold in the United States, according to FDA, although they make up only about 12 percent of the country's population. The use of multiple drugs can increase the risk of dangerous drug interactions.

Michocki says, "start low and go slow" is an adage that applies to giving older people medicines. "For the most part, with older people you're using medications to try and manage their chronic diseases like diabetes or arthritis. There's no reason to go in there and try to fix something overnight."

The rule will prove beneficial, Michocki thinks, because "after reading the special section on geriatrics, a physician who is not familiar with the drug may start out giving half the dose he was going to give in the first place."

New labels are appearing gradually, first on those drugs that FDA has determined are most likely to create problems for geriatric patients. These include psychotropic drugs such as antidepressants and antipsychotics, as well as some heart medications and nonsteroidal anti-inflammatory drugs (NSAIDs).



mined. The cause of these deaths is not known. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery

The effect of paroxetine on labor and delivery in humans is unknown.

Nursing Mothers

Like many other drugs, paroxetine is secreted in human milk, and caution should be exercised when Paxil (paroxetine hydrochloride) is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

Geriatric Use

In worldwide premarketing *Paxil* clinical trials, 17% of Paxil-treated patients (approximately 700) were 65 years of age or older. Pharmacokinetic studies revealed a decreased clearance in the elderly, and a lower starting dose is recommended; there were, however, no overall differences in the adverse event profile between elderly and younger patients, and effectiveness was similar in younger and older patients (see CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS

Associated with Discontinuation of Treatment

Twenty percent (1,189/6,145) of *Paxil* patients in worldwide clinical trials in depression and 11.8% (64/542) and 9.4% (44/469) of *Paxil* patients in worldwide trials in OCD and panic disorder, respectively, discontinued treatment due to an adverse event. The most common events (≥1%) associated with discontinuation and considered to be drug related (i.e., those events associated with dropout at a rate approximately twice or greater for *Paxil* compared to placebo) included the following:

9

term 6-week placebo-controlled trial
patients were dosed in a range of 20
day. Reported adverse events were
using a standard COSTART-based
terminology.
The prescriber should be aware that
ules cannot be used to predict the in
side effects in the course of usual m
tice where patient characteristics and
tors differ from those which prevailed
ical trials. Similarly, the cited frequenc
be compared with figures obtained
clinical investigations involving diffe
ments, uses and investigators. The cit
however, do provide the prescribing
with some basis for estimating the re
tribution of drug and nondrug factors
effect incidence rate in the population

**Table 1. Treatment-Emergent A
Experience Incidence in Placebo-C
Clinical Trials for Depressio**

Body System	Preferred Term	Pax (n=42
Body as a Whole	Headache	18
	Asthenia	15
Cardiovascular	Palpitation	3
	Vasodilation	3
Dermatologic	Sweating	11
	Rash	2
Gastrointestinal	Nausea	26
	Dry Mouth	18
	Constipation	14
	Diarrhea	12
	Decreased Appetite	6
	Flatulence	4
	Oropharynx Disorder*	2
	Dyspepsia	2
Musculoskeletal	Myopathy	2
	Myalgia	2
	Myasthenia	1
Nervous System	Somnolence	25
	Dizziness	13
	Insomnia	13
	Tremor	6

10

"Almost every drug that comes through FDA [for approval] has been examined for effects in the elderly."

— Robert Temple, M.D.
Associate Director for Medical Policy

direct benefit for older adults, who are more likely to have these conditions.

In several surveys, FDA discovered that drug manufacturers had been using older adults in their drug studies; however, they weren't examining that age group for different reactions to the drugs. Now, they do. Today, every new prescription drug has a section in the labeling about its use in the elderly.

Says Temple, "The FDA has done quite a bit and worked fully with academia and industry to change drug testing so that it does analyze the data from elderly patients. We're quite serious about wanting these analyses."

When More Isn't Necessarily Better

Of all the problems older adults face in taking medications, drug interactions are probably the most dangerous. When two or more drugs are mixed in the body, they may interact with each other and produce uncomfortable or even dangerous side effects. This is especially a problem for older adults because they are much more likely to take more than one drug. Two-thirds of adults over age 65 use one or more drugs each day, and one-quarter of them take three drugs each day.

Not all drug combinations are bad. High blood pressure is often treated with several different drugs in low doses. Unless supervised by a doctor, however, taking a mixture of drugs can be dangerous.

For example, a person who takes a blood-thinning medication should not combine that with aspirin, which will thin the blood even more. And antacids can interfere with certain drugs for Parkinson's disease, high blood pressure, and heart disease. Before prescribing any new drug to an older patient, a doctor should be aware of all the other drugs the patient may be taking.

"Too often, older people get more drugs without a reassessment of their previous medications," says Feinberg. "That can be disastrous."

There is also evidence that older adults tend to be more sensitive to drugs than younger adults are, because of their generally slower metabolisms and organ functions. As people age, they lose muscle tissue and gain fat tissue, and their digestive systems, liver, and kidney functions slow down. All this affects how a drug will be absorbed into the bloodstream, react in the organs, and how quickly it will be eliminated. The old adage "start low and go slow" applies especially to the elderly.

Older adults who experience dizziness, constipation, upset stomach, sleep changes, diarrhea, incontinence, blurred vision, mood changes, or a rash after taking a drug should call their doctors. The following suggestions may also help:

- Don't take a drug unless absolutely necessary. Try a change in diet or exercise instead. Ask your doctor if there's anything else you can do besides drug therapy for the condition.
- Tell your doctor about all the drugs you take. If you have several doctors, make sure they all know what the others are prescribing, and ask one doctor (such as an internist or family physician) to coordinate your drugs.
- Some internists and family physicians take extra training and a written examination to receive a Certificate of Added Qualification in Geriatric Medicine.
- Ask for drugs that treat more than one condition. Blood pressure medicine might also be good for heart disease, for example.
- Keep track of side effects. New symptoms may not be from old age but from the drug you're taking. Try another medication, if possible, until you find one that works for you.
- Learn about your drugs. Find out as much as you can by asking questions and reading the package inserts. Both your doctor and pharmacist should alert you to possible interactions between drugs, how to take any drug properly, and whether there's a less expensive generic drug available.
- Have your doctor review your drugs. Take all of your drugs, including dietary supplements, over-the-counter preparations, and vitamins with you on a doctor's visit.
- Ask the doctor, "When can I stop taking this drug?" and "How do we know if this drug is still working?"
- Watch your diet. Some drugs are better absorbed with certain foods, and some drugs shouldn't be taken with certain foods. Ask a pharmacist what foods to take with each drug.
- Follow directions. Read the label

every time you take the medication to prevent mistakes, and be sure you understand the timing and dosage prescribed.
- Don't forget. Use a memory aid to help you—a calendar, pill box, or your own system. Whatever works for you is best. Note: Some drugs, such as nitroglycerin, will lose their strength unless kept in the special containers supplied by your pharmacist.

Medicine and Special Needs

Arthritis, poor eyesight, and memory lapses can make it difficult for some older adults to take their medications correctly. Studies have shown that between 40 and 75 percent of older adults don't take their medications at the right time or in the right amount. About one-quarter of all nursing home admissions are due at least in part to the inability to take medication correctly.

A number of strategies can make taking medication easier. Patients with arthritis can ask the pharmacist for an oversized, easy-to-open bottle. For easier reading, ask for large-print labels. If those are not available, use a magnifying glass and read the label under bright light.

Among healthy older adults, medications may have the same physical effects as they do in younger adults.

Invent a system to remember medication. Even younger adults have trouble remembering several medications two or three times a day, with and without food. Devise a plan that fits your daily schedule. Some people use meals or bedtime as cues for remembering drugs. Others use charts, calendars, and special weekly pill boxes.

Mary Sloane, 78, keeps track of five medications a day by sorting her pills each evening into separate dishes. One is for morning pills, the other for the next evening. Then she turns each medicine bottle upside down after taking a pill so she can tell at a glance if she has taken it that day.

"You have to have a system," Sloane says. "Because just as soon as I get started taking my pills, the phone rings, and when I come back to it, I think, 'Now have I taken that?'"

Drug-taking routines should take into account whether the pill works best on an empty or full stomach and whether the doses are spaced properly. To simplify drug taking, always ask for the easiest dosing schedule possible—just once or twice a day, for example.

Serious memory impairments require assistance from family members or professionals. Adult day care, supervised living facilities, and home health nurses can provide assistance with drugs.

Cutting Costs

The cost of medications is a serious concern for older adults, most of whom must pay for drugs out of pocket. Even those who have insurance to supplement Medicare must often pay a percentage of the cost of their medicines.

For a new prescription, don't buy a whole bottle. Request starter samples from your physician, or buy just a small amount at first If you do have to switch, you won't be stuck with a costly bottle of medicine that you can't take.

For ongoing conditions, medications are often less expensive in quantities of 100. Only buy large quantities of drugs if you know your body tolerates them well. But be sure you can use all of the medication before it passes its expiration date.

Call around for the lowest price. Pharmacy prices can vary greatly. If you find a drug cheaper elsewhere, ask your regular pharmacist if he or she can match the price.

Other ways to make your prescription dollars go further include:
- Ask for a senior citizen's discount.
- Ask your physician whether there is a less expensive medication that can work as well.
- Ask your physician or your pharmacist about the availability of a generic rated as "therapeutically equivalent" by FDA.
- Get drug samples free. Pharmaceutical companies often give samples of drugs to physicians. Tell your doctor you'd be happy to have them. This is especially convenient for trying out a new prescription.
- Buy store-brand or discount-brand over-the-counter products. Ask the pharmacist for recommendations.
- Call your local chapter of the American Association of Retired Persons (AARP) and your local disease-related organizations (for diabetes, arthritis, etc.). They may have drugs available at discount prices.
- Try mail order. Mail-order pharmacies can provide bulk medications at discount prices. Use this service only for long-term drug therapy because it takes a few weeks to be delivered. Compare prices before ordering anything.

What to Ask the Doctor

Before you leave your doctor's office with a new prescription, make sure you fully understand how to take the drug correctly. Your pharmacist can also provide valuable information about how to take your medicines and how to cope with side effects. Ask the following questions:

- What is the name of this drug, and what is it designed to do? Is this a generic or a name-brand product?
- What is the dosing schedule and how do I take it?
- What should I do if I forget a dose?
- What side effects should I expect?
- How long will I be using this drug?
- How should I store this drug?
- Should I take this on an empty stomach or with food? Is it safe to drink alcohol with this drug?

Active Lives

Not all older adults are in danger of drug interactions and adverse effects. In fact, as more people live active lives well into their 80s and beyond, many take few prescribed medications or none at all. Among healthy older adults, medications may have the same physical effects as they do in younger adults. It is primarily when disease interferes that the problems with drug interactions and adverse effects begin.

To guard against potential problems with drugs, however, older adults must be knowledgeable about what they take and how it makes them feel. And they should not hesitate to talk to their doctors or pharmacists about questions and problems they have with a medication.

Says the University of Maryland's Feinberg, "We need to have educated patients to tell us how the drugs are working."